

REMARKS

Claims 1 and 4-12 are pending in the subject application. In the March 3, 2009 Office Action, the Examiner rejected all of the pending claims. Reconsideration and reexamination are respectfully requested in view of the following remarks.

In the above amendments, Applicants have requested amendment of Claim 1 and Claim 11. Specifically, Claim 1 is amended to state that the basic bioactive agent is amine-containing. Support for such amendment can be found in the subject Specification as originally-filed, for example on page 3, line 5, wherein it is stated that basic bioactive agents are preferred, including e.g. those that are amine-containing, i.e. those containing one or more amine groups. Also, in the above amendments, Claim 11 is amended to delete the clause pertaining to an amine-bearing polyester, copolyester, polyalkylene carbonate, polyether carbonate, polyether, copolyester-carbonate or combinations thereof. Support for such amendment can be found in the Specification as originally-filed, for example Page 3, lines 26-28, wherein it is indicated that the polymer in the conjugate can be a carboxyl-bearing polyester, copolyester, polyalkylene carbonate, or copolyester carbonate, as is recited now in amended Claim 11 above.

In the March 3, 2009 Office Action, the Examiner rejected Claim 1 under 35 USC 112, second paragraph, as allegedly being indefinite. The Examiner stated that recitation of the phrase “at least 50 percent” in “said absorbable liquid polymer being at least 50 percent ionically bonded together to form said liquid conjugate” is inconsistent with the reaction of liquid polymer and basic drug in the claimed liquid conjugate being equimolar.

Applicants respectfully traverse this rejection. Applicants maintain that the phrase “at least 50 percent” is not indefinite. The Examiner is not clear as to why she thinks an equimolar reaction of liquid conjugate and basic drug would be inconsistent with the phrase “at least 50 percent ionically bonded”. Looking at, for example, the first paragraph of Page 4 of the subject Specification, it is described that the bioactive agent is contacted with one or more liquid polymers under conditions effective to cause sufficient proton transfer whereby ionic conjugation . . . occurs. It is described further on Page 4 that the conjugate components are the bioactive agent and the liquid polymer. Page 4 of the Specification additionally describes that in a preferred practice these components “are

combined, e.g. admixed” . . . such that at least about 50% of the interaction between the acidic and basic moieties of, e.g. the polymer and the bioactive agent are bonded ionically. Here, the Specification states that “in another embodiment, said liquid conjugate in this regard is a composition.” Thus, “at least 50 percent” is clear in its meaning, that the claimed conjugate is a composition comprising the bioactive agent and the liquid polymer wherein at least 50 percent of the interaction between the moieties thereof are ionically bonded.

The Examiner also rejected Claim 11 under 35 USC 112, second paragraph, stating that since Claim 1, from which Claim 11 depends, requires ionically bonded liquid polymer and basic drug, it is unclear how an amine bearing polymer will form an ionic bond with the drug. This rejection is moot in light of the amendment to Claim 11 requested above.

The Examiner further rejected Claim 1 under 35 USC 112, second paragraph, due to the phrase “basic drug”. According to the Examiner it is unclear if the drug is alkaline and thus basic in nature or bears an amino group. This rejection is moot in light of the amendment to Claim 1 requested above.

The Examiner in the March 3, 2009 Office Action maintained the rejection of the Claims as being obvious under 35 USC 103 over Shalaby (US Patent 5,714,159) in view of Kim et al. (US Patent 6,232,304). The Examiner reiterated the arguments previously presented, i.e. that Shalaby discloses a “Component A” which is a molecular chain that can be optionally comprising carboxylic end-groups to facilitate ionically binding a biologically active agent or drug. The Examiner relies on Kim et al. for the teaching of ziprasidone as a biologically active agent.

Applicants traverse the rejection of the Claims as obvious over Shalaby in view of Kim et al. The Examiner has emphasized that the “Component A” of Shalaby can optionally comprise carboxylic end-groups. Applicants’ invention as recited in the claims relates to a *liquid* conjugate (emphasis added). Shalaby does not teach a liquid conjugate. The conjugates of Shalaby form a compliant hydrogel mass on contact with aqueous environment. Furthermore, Shalaby does not disclose the particular polymers which are now recited in Applicants’ Claim 1 pursuant to the prior Amendment. The

Examples in the subject Specification do not gel and remain essentially liquid when contacted with an aqueous medium.

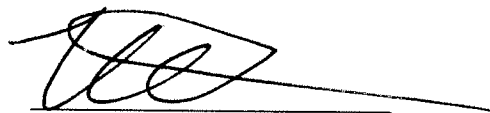
The Examiner has argued that the features upon which Applicants rely are not recited in the rejected claims. However, that is not correct because Claim 1, from which all other Claims depend, clearly recites that the claimed conjugates are *liquid* conjugates (emphasis added).

The Examiner further alleged in the March 3, 2009 Office Action that the Claims are not commensurate with the scope of the disclosure because not all or every generically claimed polycarbonate, polyester carbonate or polyester carrying two or more carboxyl has been disclosed to form a liquid conjugate. Applicants traverse this allegation because Applicants are not legally required to exemplify each and every claimed embodiment.

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of the Claims as amended herein. To the extent the Examiner believes it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

No fee is believed necessary in connection with this Amendment. However, if any fee is deemed necessary, the Commissioner is hereby authorized by this paper to charge such fee (or credit any overpayment) to Deposit Account 16-1445.

Respectfully submitted,



Kristina L. Konstas
Attorney for the Applicants
Reg. No. 37,864
Phone: 212-733-6380

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Pfizer Inc.
Patent Department
150 East 42nd Street
Mail Stop: 150/05/49
New York, New York 10017